UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:18-op-45090 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:17-op-45004 (N.D. Ohio)

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

REPLY TO MEMORANDUM OF LAW IN SUPPORT OF RITE AID OF MARYLAND'S MOTION FOR SUMMARY JUDGMENT (ECF 1870 & 2185)

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Plaintiffs' response confirms the unique weakness of their claims against Defendant Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid" or "Rite Aid Mid-Atlantic"). Plaintiffs' claims allege deficiencies in Rite Aid's suspicious order monitoring ("SOM") system, but they present no expert testimony regarding this system. Plaintiffs' response that systems for monitoring opioid distribution pursuant to a complex regulatory regime are within the "common knowledge" of jurors is facially absurd and at odds with arguments they made elsewhere.

Two of Rite Aid's arguments go entirely unanswered. Plaintiffs do not dispute Rite Aid's contention that the statutory public nuisance claim, which seeks injunctive relief, is moot because Rite Aid stopped distributing opioids in 2014. Mot. at 7 n.4 (ECF 1870). Plaintiffs also do not dispute that their injury through criminal acts claim cannot survive because there is no evidence showing Rite Aid violated Ohio Revenue Code § 2925.02(A)(3). Mot. at 8. At the least, Rite Aid must receive summary judgment on these claims.

Nor do Plaintiffs have any response to Rite Aid's limited activity within the limitations period, given that Rite Aid distributed a miniscule percentage of opioids in the two counties, or their failure to identify injuries caused by Rite Aid's distribution of allegedly "suspicious" orders. Rite Aid's motion for summary judgment should be granted.

I. Plaintiffs' Failure to Present Expert Testimony Regarding Rite Aid's Suspicious Monitoring System Requires Summary Judgment.

Plaintiffs present no expert testimony concerning Rite Aid's SOM system. As a result, the testimony of Rite Aid's expert, Dr. Jena, stands unrebutted. Mot. at 5-6. Summary judgment is required.

Plaintiffs concede that their claims require expert testimony unless the breach was "so obvious as to be easily recognized by the average juror" and "render expert testimony

unnecessary." Resp. at 2 (ECF 2185). The matter must be "within the comprehension of a layperson" for expert testimony to be unnecessary. *Ramage v. Cent. Ohio Emergency Serv., Inc.*, 592 N.E.2d 828, 833 (Ohio 1992). Plaintiffs' claims do not fit within this exception.

As Rite Aid explained in its motion, the design and operation of a SOM system is a matter wholly unfamiliar to lay jurors, particularly given the complex regulatory environment. Like other professional standards of performance, expert testimony is necessary. *Ramage*, 592 N.E.2d at 833.

Plaintiffs know this—elsewhere in their briefing, Plaintiffs acknowledge that expert testimony is necessary due to the "complex regulatory scheme applicable to opioid manufacturers and distributors, which is likely unfamiliar to a layperson." ECF 2114 at 13 (Plaintiffs' opposition to Whitelaw Daubert motion). Indeed, by designating experts to testify regarding other defendants' SOM systems, Plaintiffs necessarily concede this testimony would "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a); *see* Rafalski Rpt. (ECF 2000-22); Whitelaw Rpt. (ECF 2000-26).

Plaintiffs' argument that a lay juror could conclude that "a system that never identifies a suspicious order is no system at all," Resp. at 4, is absurd. Rite Aid also identified no tiger attacks or alien abductions at its distribution center. Under Plaintiffs' reasoning, the failure to identify either occurrence somehow means that both were occurring but undetected.

Plaintiffs' assertion (without citation to evidence) that Rite Aid "developed, but never implemented, a suspicious order monitoring system," Resp. at 6, is belied by the record. Plaintiffs apparently refer to a project to consolidate Rite Aid's existing SOM system. But evidence showed that "those controls were already in place" prior to this project. Belli Tr. 160:10-19 (ECF 1956-20) ("[T]his project was not created to create [sic] effective controls."); *see also* Chapman Tr. 113:23-114:15 (ECF 2169-10) ("[I]t would have folded all of those processes together[.]").

Plaintiffs' citation (at 3-4) to Janet Hart's testimony about the asset protection program only underscores the need for expert testimony. As Rite Aid's expert Dr. Jena explained, Rite Aid Hdqtrs Corp's asset protection program supplemented its suspicious order monitoring controls and was designed as an additional protection against internal theft. Jena Rep. ¶¶37-38 (ECF 1939-15).

It is unsurprising that Rite Aid would have no suspicious orders when it only distributed to its own stores (rather than pill mills or internet pharmacies), never distributed Schedule II drugs, passed its DEA and Maryland audits with flying colors, and did not increase its distribution over the 2006-2014 time period. As Plaintiffs acknowledge, one of the key purposes "of a SOM program is to . . . ensure that [customers] are legitimate customers," ECF 2253 at 15, and Rite Aid undeniably knew its customers.

Plaintiffs present no evidence of any suspicious order that Rite Aid's SOM system should have identified. Instead, they (at 3-5) conflate orders **distributed to** pharmacies by Rite Aid Mid-Atlantic (the defendant) with prescriptions **filled by** pharmacies owned by Rite Aid of Ohio (which has not been sued). Plaintiffs allege that pharmacies filled suspicious prescriptions. *See* Resp. at 3 (arguing that Rite Aid "failed to ever identify or report any of the suspicious prescribers' orders as suspicious"). But Rite Aid Mid-Atlantic is only—and has only been sued as—a distributor, and it only distributed to Rite Aid pharmacies. It never received "orders" from prescribers, suspicious or otherwise, and it never distributed to prescribers. Prescriptions filled at Rite Aid of Ohio pharmacies are just that—prescriptions; they are not "orders" placed to the distribution center.

The document Plaintiffs cite regarding Dr. Harper (at 4) is an email exchange concerning a threshold increase requested of McKesson by a Rite Aid of Ohio pharmacy, which has nothing to do with Rite Aid Mid-Atlantic. And the two pharmacists losing their licenses (cited at 4) do not

demonstrate that Rite Aid should have identified orders from those pharmacies as suspicious.[1] Plaintiffs have produced no evidence showing that either pharmacist was diverting opioid pills at a volume or frequency that would have caused the pharmacy to send orders to the distributor that should have been flagged as suspicious.

Nor does the *Masters* decision assist Plaintiffs. Plaintiffs' characterization of Rite Aid's supposed obligations under *Masters* is incorrect for the reasons set forth in ECF 2159, including that *Masters* involved distribution of opioids to pill mills, not distributions to retail pharmacies. Rite Aid also stopped distributing all narcotics in 2014, long before the *Masters* decision issued.

Plaintiffs have no SOM expert discussing Rite Aid. Although they identify the general testimony of Rafalski and Whitelaw, Resp. at 5-6, they do not argue that Rafalski's testimony can be generalized to Rite Aid's SOM system. And even if Whitelaw's report set forth a generalized standard of care, jurors would need the guidance of expert testimony in applying this standard to Rite Aid's SOM system. Nor do Plaintiffs identify any evidence regarding Rite Aid's SOM system to which any "standard of care" could be applied. Any deficiencies in Rite Aid's SOM system were far outside the common experience of a lay juror. Plaintiffs needed—but failed to present—expert testimony, and summary judgment is warranted.

II. Plaintiffs Have No Answer to the DEA and Maryland Audits of Rite Aid.

Plaintiffs cannot deny that Rite Aid was regularly audited by DEA, by the Maryland Division of Drug Control, and by the Maryland Board of Pharmacy. In attempting to evade this evidence, Plaintiffs describe it incorrectly. Far from involving "unidentified Rite Aid employees" and being unrelated to suspicious order monitoring, Resp. at 8, an individual, Keith Frost, testified

[1] Moreover, demonstrating the effectiveness of Rite Aid's controls, both these pharmacists were detected by Rite Aid and reported to DEA and the Ohio Board of Pharmacy. *See* ECF 2149 at 90.

what he was personally told by DEA agents who reviewed Rite Aid's SOM system. Frost Tr. 300:8-304:22 (ECF 2169-14).

DOJ's letter to this Court admits, as did DEA witnesses, that these audits reviewed the registrant's SOM system "to determine whether that system complies with the regulations." It is irrelevant that the audits may have "focused on the site's physical security and record-keeping," Resp. at 8 (quoting DOJ letter), because they also covered the SOM system. And even if the audits were "not **designed to** endorse [SOM] systems," Resp. at 8 (emphasis added), DEA auditors in fact endorsed Rite Aid's system. And even if the auditors had remained silent, DEA's failure to identify any deficiencies in Rite Aid's SOM system during these audits is highly relevant.

DEA reviewed the very SOM systems that form the basis of the Plaintiffs' claims against Rite Aid. None of the audits identified any deficiency in Rite Aid's system, and Rite Aid's evidence showed that the results were uniformly favorable. As Frost testified, "[T]hey were very, very happy with the way we had our controls in place, and they wished other places did the same thing we did." Frost Tr. 87:19-88:6 (ECF 2169-14). To the extent Plaintiffs complain of hearsay, Rite Aid welcomes the opportunity to present testimony directly from the DEA agents who conducted the audits and personally praised Rite Aid's system.[2]

At the summary judgment stage, Plaintiffs have presented no evidence—from any witness, expert or fact—criticizing Rite Aid's SOM system. The only evidence regarding the effectiveness of that system is the testimony of Rite Aid's expert, Dr. Jena, and the flawless audits from DEA and Maryland agencies. Plaintiffs failed to develop evidence necessary to support their claims, and summary judgment is warranted.

[2] Rite Aid sought DEA documents and testimony related to these audits, and its motion to compel has been pending since June 14, 2019.

III. Summary Judgment in Rite Aid's Favor Is Required on Causation.

Plaintiffs also fail to identify evidence creating a question of fact regarding causation. Although Plaintiffs incorporate arguments from their opposition to the causation summary judgment motions, that response only includes four references to the Pharmacy Defendants' motion and certainly contains no evidence individually showing causation as to Rite Aid.

For any of their claims, Plaintiffs fail to connect the miniscule amount of opioids that Rite Aid distributed within the limitations period (0.048% of total MMEs) to their injuries; show that any diversion occurred from any suspicious shipment by Rite Aid; or demonstrate that any such a small percentage of diversion was a "substantial factor" in their harm.

The exhibits cited by Plaintiffs do not establish causation. A hypothetical example used in training materials of a dental surgery patient becoming addicted does not establish causation between a failure to detect suspicious orders and the alleged harms in this case. Resp. at 10 (citing Exh. 8). And the deposition testimony merely establishes that Rite Aid's 30(b)(6) witness acknowledged that a purpose of preventing diversion is to protect public health. ECF 1962-22 at 23:19-23. Even if Plaintiffs had produced evidence of diverted suspicious orders, they needed to show (through expert testimony) that in light of Rite Aid's small market share that those diverted suspicious orders actually caused the injuries they allege. They have failed to do so.

Conclusion

Plaintiffs have failed to present the expert testimony necessary to show deficiencies in Rite Aid's suspicious order monitoring system and failed to present evidence showing any harm (much less substantial factor causation) caused by any alleged breach by Rite Aid, which distributed only a small volume of opioids for a limited time and only to its own stores. Summary judgment is warranted in favor of Rite Aid on all claims.

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Respectfully submitted,
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